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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S and ANTON MAYR,	)	
Plaintiffs,	)	C.A. No. 05-614-SLR
v.	)	***FILED UNDER SEAL —***
ACAMBIS INC. and ACAMBIS PLC,	)	***CONTAINS CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER***
Defendants.	)	

BAVARIAN NORDIC'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS, OR IN THE ALTERNATIVE FOR SUMMARY JUDGMENT, ON ALL CLAIMS

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January 3, 2007

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I. SUMMARY OF ARGUMENT

Defendants, Acambis Plc and Acambis Inc. (collectively "Acambis"), have moved for summary judgment on the issues of conversion and unfair competition. *See* D.I. 111. Plaintiff Bavarian Nordic A/S ("BN") has also filed for summary judgment on the issue of conversion. *See* D.I. 114. While both parties assert that material facts are not in dispute, Acambis' position is based on several material misstatements of the facts, and confusion as to the law. Acambis' position is more or less based on its attorneys' interpretations of other peoples' actions, and not on direct, reliable testimony.

On the issue of conversion, the facts are not in dispute, but they point heavily in favor of finding that Acambis converted BN's tangible property, i.e., sample vials of the particular vaccinia virus strain called MVA 572. Acambis' argument that conversion cannot be found where an intangible right is involved, i.e., the "right to commercialize" a virus, fails *ab initio*, since BN is not asserting this intangible right. Instead, BN is asserting that the tangible thing called MVA 572 was converted by Acambis. BN asserted its intangible right to commercialize by bringing a patent infringement action at the U.S. International Trade Commission ("ITC") against Acambis. Acambis is simply confused about the difference between intellectual property (patent claims) and personal property (conversion claims), the latter of which is involved in this Court.

On the specific facts related to conversion, Acambis gets it wrong at every critical juncture. The facts presented by BN in its Opening Brief in support of its motion for summary judgment (D.I. 115) clearly establish that Prof. Dr. Anton Mayr developed and owned all rights to MVA 572, in contradistinction to Acambis' argument that other parties "own" the strain. None of these purported other owners have offered direct, credible testimony that contradicts Prof. Mayr's claim of ownership.

Furthermore, the facts clearly show that Prof. Mayr delivered a sample of MVA 572 to Dr. Bernard Moss of the U.S. National Institute of Health ("NIH") "for research purposes only."

This fact is supported, *inter alia*, by Prof. Mayr's direct, sworn testimony. The only person who could contradict Prof. Mayr with direct, credible evidence would be Dr. Moss, but he has refused to provide testimony in spite of BN's persistent efforts to compel discovery. Indeed, on December 13, 2006, Magistrate Judge Day of the U.S. District Court for the District of Maryland ruled that Dr. Moss did not have to comply with BN's discovery requests because his testimony would be potentially harmful to the NIH:

> Assuming all of the representations of Bavarian Nordic are true, and I do in large measure here, it is still quite apparent to me that allowing Dr. Moss to testify would more likely than not reveal evidence that is contrary to the interests of NIH. There is the potential breach of non-disclosure agreements. There is the potential complicity with Acambis. There is potential tortous [sic] conduct, which is not protected by sovereign immunity.

Ex. A, Motion to Compel Hearing Tr. at 51. If Dr. Moss had nothing to hide, and had done nothing inappropriate, the NIH would not have prevented Dr. Moss from giving testimony. It is no stretch to draw a simple negative inference from NIH's refusal to allow Dr. Moss to testify, that Dr. Moss' testimony could only be damaging to Acambis' position on the issue of conversion. This negative inference makes all the more sense given that Dr. Moss was a paid consultant to Acambis.

Finally, as will be pointed out below, Acambis is wrong about most of the facts relied upon in their briefing papers. One error that is particularly galling is Acambis' claim that their product is "a proprietary vaccine designed and produced by Acambis." (Acambis Opening Br., D.I. 112, at 2.) Nothing could be further from the truth. Acambis simply took what it received from Dr. Moss and gave it to its manufacturing partner, Baxter, which used BN's patents as a roadmap on how to make a commercial vaccine. Although the ITC's decision is not yet final, the initial determination included a finding that Acambis' product infringed BN's patents.

There is one thing that perhaps both parties can agree on, which is that there is not a great deal of case law involving facts similar to those involved in the present case. Conversion claims

typically involve inanimate objects, not living organisms. The "living" aspect of the specific proprietary material in this case makes the conversion claim critical, because once the vial of MVA 572 is converted inappropriately, the viral products contained in the vial can replicate and produce millions of doses of valuable small pox vaccine.

Thus, damages in this case are based on the commercialization of what was converted, but the act of conversion simply relates to the receipt by Dr. Moss of tangible vials of specific vaccinia virus, MVA 572, from Prof. Mayr, and Acambis' receipt of the progeny of that virus.

II. PROCEDURAL BACKGROUND AND DISPUTED FACTS

In its opening brief, Acambis sets forth the procedural background of this case, including 34 paragraphs of "undisputed background facts" which purportedly relate to Bavarian Nordic's claims. *See* D.I. 112 at 4. Although BN does not generally dispute Acambis' version of the procedural background of this case, BN clarifies below several incorrect assertions made by Acambis with respect to both BN's legal claims and the purported background facts.

First, Acambis attempts to improperly narrow the legal claims that BN asserts in this procedure by stating that all of Bavarian Nordic's claims relate to Acambis' use of the MVA 572 virus strain it received from NIH. Acambis attempts to confuse the legal issues by suggesting that, for example, the conversion claim refers to intellectual property as opposed to personal property. This is plainly incorrect. BN alleges tortious conversion of biological material, as such, unfair trade practices and unfair competition under the Lanham Act. *See* D.I. 85, First Amended Complaint (filed Aug. 23, 2006).

Secondly, Acambis also seems to suggest a novel type of intellectual property right, namely a commercial right to use. This is particularly nonsensical. It is well established that intellectual property, or intangible rights, refers to patents, trademarks, copyright and trade secrets. A commercial use refers to the scope of a right provided, or not provided, be it with respect to property or intellectual property. It is not an intellectual property right in itself. In this case, the issue of commercial use relates to the limited right provided to Dr. Moss to use a

property right, namely the proprietary MVA 572 material. Only a limited right to use this proprietary material was provided to Dr. Moss and that was for research purposes. In particular, there was no transfer of property rights to the material to Dr. Moss, or the NIH. Accordingly, the NIH had no property rights that it could transfer to Acambis in its Material Transfer Agreement. Thus, the MTA between the NIH and Acambis is null and void.

Moreover, the unfair trade practices and unfair competition claims are certainly not limited to improper use of the MVA 572 virus. BN has, for example, alleged that Acambis exerted improper influence on a NIH official to: (1) ensure the timely provision of the MVA 572 material from the NIH to Acambis; (2) obtain information about the status of Bavarian Nordic's business with NIH and developments related to Bavarian Nordic's MVA program, immediately before NIH's first Request for Proposal was issued; and (3) obtain institutional information regarding the importance of showing freedom to operate with respect to BN's rights to achieve an award under the RFP program. BN also alleges that Acambis mislead the NIH by not disclosing the risk Acambis would encounter in Europe with respect to a stop in supply of its MVA3000 product based on European patents and lawsuits. In particular, the U.S. government has no jurisdiction and thus cannot influence, for example, an Austrian court, the country of manufacturing, based on any public policy argument should an infringement suit prove successful.

Acambis, prior to the release of the first RFP, had not yet developed an MVA-based smallpox vaccine. Discovery conducted in the Delaware case, however, has shown that Dr. Bernard Moss, an employee at NIAID, provided Acambis with Bavarian Nordic's MVA strain, and was a consultant to Acambis, at least through its corporate predecessor OraVax. The record shows that Acambis evaluated three prospects to acquire the MVA material: (1) through a license with BN at a price tag; (2) through a license with Therion at a price tag (and, according to Acambis' own legal evaluation, with a cloud regarding ownership); and (3) for free through its prior official consultant Dr. Moss who, based on internal e-mails, still assisted Acambis. Ex. B,

Moss-Monath emails. Acambis chose to acquire the MVA 572 for free from the NIH despite knowledge of the issue of ownership. It is telling that Acambis, according to an internal e-mail from Dr. Monath, recognized that Acambis should compensate Dr. Moss for everything he had done for Acambis. Ex. C, Monath email at AC0450441 [redacted] In contrast, Dr. Monath never accredited the same courtesy to Prof. Mayr, notwithstanding that Prof. Mayr created the man-made species at issue referred to as MVA.

Dr. Moss acquired the MVA strain from Professor Mayr. Dr. Moss requested samples of MVA in 1995 and in 2001 from Professor Mayr, who generously complied with both of Dr. Moss' requests. Prof. Mayr, however, provided these proprietary MVA samples to Dr. Moss for research purposes only. In particular, Prof. Mayr never transferred ownership. There is no law requiring a written restriction when providing property to a third party for other purposes than transferring ownership. Rather, the law should safeguard a proprietor from any "accidental" transfers of ownership. Acambis was only able to develop its own MVA-based smallpox vaccine MVA3000 by converting the MVA strain it received from Dr. Moss, thereby violating BN's and/or Prof. Mayr's property rights in MVA.

Acambis improperly acquired specific proprietary MVA material from the NIH referred to as MVA 572 which is owned by BN. BN acquired its ownership of the MVA virus material from Prof. Mayr in November 2002, who created the new live vaccinia virus species he identified as Modified Vaccinia Ankara ("MVA") from the completely different vaccinia species CVA, which preexisted in nature. Prof. Mayr is also a co-plaintiff in this case. Prior to the transfer of ownership between Prof. Mayr and BN, BN had exclusive license to commercially use Prof. Mayr's proprietary MVA material. D.I. 116 at Ex. K, Mayr-BN 1996 Agreement.

However, it is irrelevant for finding conversion in this case whether BN owned or had exclusive rights at the time Prof. Mayr provided the MVA 572 material to Dr. Moss for two

reasons. First, Prof. Mayr is a co-plaintiff in this case. Second, the 2002 agreement transfers Prof. Mayr's ownership of MVA to BN, *i.e.* Prof. Mayr's rights becomes BN's rights, including the proprietary right Prof. Mayr had to the specific MVA 572 material/vial he provided Dr. Moss with. D.I. 116 at Ex. L, Mayr-BN 2002 Agreement. Accordingly, either BN or Prof. Mayr enjoyed legal ownership to the MVA 572 both at the time the MVA 572 was provided to Dr. Moss and when the propagated virus material referred to in the MTA as MVA 572 was provided to Acambis.

Acambis alleges that Prof. Mayr testified that he was not aware he had been added as a co-plaintiff in this case and that he was not seeking any relief. Acambis' Op. Br. (D.I. 112), at 3. It is true that Prof. Mayr is not seeking any relief separate and apart from Bavarian Nordic's damages. The reason is evident. Prof. Mayr recognizes that he has transferred his ownership and, thus, his rights to monetary damages and injunctive relief to BN. Prof. Mayr testified during his deposition that his being added as a co-plaintiff was discussed at a meeting with BN's counsel, in which his personal German attorney [redacted] was also present. Ex. D, 9/21/06 Mayr Depo at 59:11-61:10; Ex. E, 9/21/06 Wulff Depo. at 147:10-148:6. Prof. Mayr has assisted in this case, albeit his participation has been somewhat limited due to his age and fragile health. Indeed, Acambis has propounded discovery on Prof. Mayr and he has submitted and verified interrogatory responses. Prof. Mayr has also voluntarily appeared for two depositions, the first one several months before he was a plaintiff.

Additionally, Acambis mischaracterizes and/or misstates certain aspects of the record in its purported 34 "undisputed" background facts. Moreover, several of these aspects are irrelevant to the legal issue they allegedly pertain to. However, if the court should consider any of these aspects relevant, there are certainly material facts in dispute, and dismissal of BN's claims based thereon is not appropriate. BN will address the most flagrant ones below.

Regarding paragraph nos. 2-6, which generally relate to the development of MVA and Prof. Mayr's ownership, BN notes the following:

Acambis attempts to confuse the issue of Prof. Mayr's ownership to his novel vaccinia virus species MVA by mixing statements referring to different decades and regarding different virus species. Prof. Mayr worked with the CVA virus, which preexisted in nature and not MVA during the time he was an assistant in the early 1950s at the Bavarian State Vaccine Institute under the supervision of Prof. Herrlich. Prof. Mayr did not create MVA, nor did he begin to create MVA by passaging CVA in CEF cells while he was an assistant at Bavarian State Vaccine Institute. In fact, Prof. Mayr has worked with several virus species post his graduate studies at the Bavarian Vaccine Institute in the early 1950s, *i.e.* different vaccinia viruses but also, for example, camelpox and the myxoma virus in an attempt to create novel useful viruses by passaging these viruses.

The development of his life achievement MVA and the creation of MVA 572 specifically occurred during the time period of 1960-1974, as noted in the 1975 Mayr et al. article. D.I. 116 at Ex. E, Mayr et al., *Infection* (1975). Furthermore, Prof. Mayr presented the article, "History of Variola, Smallpox Eradication and MVA," at the poxvirus conference at Elmau on January 28, 1999, which was attended by virtually every peer scientist in the poxvirus field. D.I.116 at Ex. F. This article states: "[i]n the period from 1960-1974, the author (**A. Mayr**) succeeded in attenuating the dermal vaccinia strain **Ankara (CVA)** through 572 continuous passages in primary chicken embryo fibroblast cultures (CEF) . . ." *Id.* at BNITC00091893. Table 4 shows that the CEF passaged Ankara strain is given the name MVA (Modified Vaccinia Ankara) in 1974, and attributes the MVA 572 passages to A. Mayr. *Id.* at BNITC00091901. Prof. Mayr's laboratory notes have been produced in this case and detail his creation of MVA. Ex. F, Mayr Lab Notebook. Moreover, Acambis has acknowledged Prof. Mayr as the creator and rightful owner of MVA in the ITC investigation. D.I. 116 at Ex. A, JSUF ¶¶ 17, 69.

The evidence on record overwhelmingly shows that in the 1970s, after years of hard work to create a novel vaccinia virus species, Prof. Mayr collaborated with Dr. Stickl, a medical doctor at the Bavarian Vaccine Institute, who assisted with the clinical trials for MVA

used as a pre-vaccine for smallpox. MVA 572 was not developed at the Bavarian Vaccine Institute and is not the property of the Institute. D.I. 116 at Ex. C, Mayr Declaration at ¶¶3-5. Prof. Mayr is not a medical doctor and as such he is unable to personally perform clinical studies which require the assistance of a medical doctor. Acambis is well aware of this fact because Acambis also collaborates with various medical doctors and research institutions for its clinical trials of MVA3000. Surely, Acambis does not imply that these medical doctors and research institutions therefore would own MVA3000, including the MVA3000 stored in its own freezers.

Furthermore, Acambis' statements in these paragraphs are irrelevant with respect to any issue in this case, which concerns material in a specific vial containing MVA 572 that was provided from Prof. Mayr, having been stored in his freezer, to Dr. Moss for research purposes. D.I. 113, Ex. 25, Moss letter to Mayr (Aug. 3, 2001). These paragraphs provide no logical reasoning, consistent conclusion or valid point when it contends that the MVA viruses after passage MVA 572 are genetically identical. Moreover, these paragraph is also incorrect and misleading because the evidence on record shows that all MVA viruses after passage 572 are not genetically identical. *See* BN Scientific Reports attached as Ex. F; In fact, the PCR sequencing technology was not even invented in 1975. For example, the sequences and replication characteristics of the viruses may not be the same.

MVA 572 was used as a pre-vaccine, not a stand-alone vaccine, at a very low dose by the Bavarian State Vaccine Institute to vaccinate 120,000 individuals in the early 1970s. This low dose vaccine approach was never tested on severely immuno-compromised individuals such as HIV patients. Furthermore, none of the data generated from these vaccinations by the Bavarian State Vaccine Institute support the use of MVA as a stand-alone vaccine for smallpox. Prior to Bavarian Nordic's groundbreaking research on MVA, it was thought that MVA could only used as a pre-vaccine, *i.e.* administered in a low dose prior to vaccinating with the fully replicating vaccinia viruses such as Dryvax to protect against smallpox. Bavarian Nordic later

developed its own vaccination regime based on data showing that MVA could be used as a stand-alone vaccine against smallpox, *i.e.* without the need to also administer the fully replication competent vaccinia viruses such as Dryvax. Accordingly, BN's vaccination regime can be used for the immuno-compromised using its patented MVA based small pox vaccine MVA-BN.

Lastly, Acambis admits that Prof. Mayr possessed stocks of MVA 572 as a result of his work. This is correct. As the creator and rightful owner of MVA, Prof. Mayr had a limited supply of MVA 572 in his freezer in Germany. *Id.* Prof. Mayr took diligent precautions to prevent unauthorized use of his MVA 572 by depositing a limited amount of MVA 572 for research purposes only at the ECACC.

Regarding paragraph nos. 7-12, which generally relate Prof. Mayr's distributions of MVA to fellow scientists for research purposes, BN notes the following:

Again, these statements are irrelevant with respect to any issue in this case, which concerns material in a specific vial containing MVA 572 that was provided from Prof. Mayr, having been stored in his freezer, to Dr. Moss for research purposes. D.I. 113, Ex. 25, Moss letter to Mayr (Aug. 3, 2001). Prof. Mayr is a professor and a research scientist, who has distributed limited amounts of MVA to fellow scientists at research institutes strictly for research purposes. D.I. 116 at Ex. C, Mayr Declaration at ¶ 6.

Prof. Mayr testified that, when asked for samples, he did not have to explicitly state that the requestor was not permitted to use the material for anything but research purposes. Mayr Dep., Ex. G at 45, lines 16-21. In fact, most publications require scientists to make samples of material described in papers available to other scientists for research. However, it is counterintuitive for a commercial company to suggest that absent a written restriction from a creator and/or owner of valuable biological material the material would be free for the company to capitalize on, thereby avoiding the time consuming and costly research and development phase for free, *i.e.* without compensating the developer and/or owner. For example, Prof. Mayr would

provide MVA for research purposes for testing and then if any research institution or company would be interested in commercialization a license agreement would be executed.

Sutter's thesis refers to MVA 574, not MVA 572. Ex. H, Sutter's Thesis at AC0564047, ¶3.2. While he was a graduate student working in Prof. Mayr's laboratory, Sutter's research was done at the direction and supervision of Prof. Mayr. Ex. D, 9/21/06 Mayr deposition at 28:5-10. Therefore, any MVA material used by Sutter belonged to Prof. Mayr. MVA F6 has not been widely distributed and is not in the public domain. Although Sutter has published articles about the material that was central to his thesis, he has been unwilling to freely distribute MVA F6. Ex. I, ITC Hearing Transcript, May 9, 2006, at 310:2-6. It is also not in any public depository. BN CEO Peter Wulff has repeatedly testified that he was mistaken regarding the availability of MVA F6. Ex. J, ITC Hearing Testimony, Tr. at 163:10-164:16 (Wulff). Wulff's incorrect statements are based on the faulty assumption that BN's competitors, for example, Acambis and Transgene, had the MVA F6-580 strain.

Prof. Mayr provided MVA 572 to [redacted], a non-profit organization, in 2002 for research purposes only. Ex. K, 02/19/06 Chaplin deposition at 105:16-106:21. Moreover, [redacted] Ex. E, 9/21/06 Wulff deposition at 176:9-180:17. Subsequently, BN has informed [redacted] of its ownership rights in MVA and its intention to enforce these rights if necessary. [redacted] however is not using MVA 572 and has not commercialized any product containing MVA 572. Ex. E, 9/21/06 Wulff Deposition at 182:10-183:5.

Regarding paragraph nos. 13-16, 20-22 which relate to Mayr's transfer of MVA to Dr. Moss at NIH, BN notes the following:

Prof. Mayr transferred MVA to Dr. Moss at NIH for research purposes in 1995 and again in 2001. Dr. Moss' letter to Prof. Mayr requesting MVA in 1995 specifically referenced Moss' vector work but did not reveal any intention regarding smallpox. Prof. Mayr testified that "I

never assumed when I sent samples or a sample to NIH, no matter which sample it was, that NIH would use it for commercial purposes ….I also have no information that NIH pursues commercial purposes." D.I. 116 at Ex. G, Mayr deposition at 73-74.

Prof. Mayr also testified that it was customary in the scientific community for scientists to exchange materials for research purposes without documentation or without explicitly stating that the material was only to be used for research materials. Ex. D, Mayr deposition at 45:16-21. Additionally, most publications require scientists to make samples of material described in papers available to other scientists for research.

Prof. Mayr wrote to Dr. Moss in November 2002 confirming his expectation that the MVA Mayr provided to Moss would be used for research purposes only. D.I. 116 at Ex. Y, Mayr letter to Moss dated Nov. 2002. Dr. Moss responded to Prof. Mayr over five months later, after NIH's OTT completed its internal investigation concerning NIH's right to transfer the MVA strain to Acambis. Prof. Mayr has maintained that he transferred MVA to Dr. Moss, as a fellow research scientist, for research purposes only.

Therion's Linda Gritz testified in her deposition that she sought MVA 572 from Dr. Moss at the NIH, but he told her that she had to get written permission from Prof. Mayr before he could do so. Her letter to Prof. Mayr, read [redacted] However, she acknowledged that Prof. Mayr did not give his permission, when asked, and as a consequence, Dr. Moss did not transfer to Therion any of the MVA 572 sample he received from Prof. Mayr. *See* D.I. 116 at Ex. W, Gritz Dep., at 146:11-147:5.

Regarding paragraph nos. 23-25, which relate to the transfer of MVA by the NIH to Acambis, BN notes the following:

The Materials Transfer Agreement ("MTA") executed between NIAID/NIH and Acambis for MVA 572 specifically states that the virus is being provided "as is." *See* D.I. 116 at Ex. V,

Materials Transfer Agreement. The MTA states, in part, "3. NIAID [National Institute of Allergy and Infectious Disease, an institute at the NIH] hereby grants to Recipient [Acambis] worldwide, non-exclusive rights to make, have made, and use the Materials and to make and have made, to use and have used, to sell and have sold, and to offer to sell Commercial Products in the field of Use of Smallpox Vaccines." *Id.* The MTA, however, provides no warranty to Acambis with respect to freedom to operate. *Id.* In fact, the MTA requires Acambis to indemnify the government relating to use of the virus stock and prevents Acambis from taking steps to bring the government into a lawsuit involving the virus stock. *Id.* Michael Mowatt of NIH/OTT confirmed that NIH provided Acambis no warranty regarding freedom to operate to use the strain in a letter to Acambis employee Roger McAvoy. Ex. L, Mowatt letter to McAvoy dated 01/17/03.

Both BN and Prof. Mayr advised NIH of their ownership rights in MVA. Ex. M, Mayr letter to Mowatt dated 11/06/02; Ex. N, Wulff letter to Montagne dated 03/27/03. In addition, Prof. Mayr wrote to Dr. Moss to confirm his expectation that the MVA he provided Moss was restricted to research purposes only. D.I. 116 at Ex. Y, Mayr to Moss letter dated 11/06/02. NIH, therefore, was on notice that they had no right to transfer the MVA Dr. Moss received from Prof. Mayr. Nonetheless, any "decision" made by the NIH is irrelevant to the issue of ownership and rights, only a court can make a judgment.

Regarding paragraph nos. 26-28,which relate to the agreements Between Mayr and BN, BN notes the following:

Acambis continues to allege that there is a lapse in time between the Mayr-BN agreements during which Mayr sent MVA 572 to the NIH. As explained in BN's opening brief in support of its motion for summary judgment (D.I. 115), this argument lacks merit. Prof. Mayr is a party to this case. As such, it does not matter whether any of the Mayr-BN agreements should be treated retroactively or not. To the extent that Acambis converted MVA strains before particular BN agreements, Prof. Mayr would have the right to recover. Alternatively, if the agreements have retroactive effect, then BN would have the right to recover.

The 2004 "Supplemental Agreement" was executed in part because it was broader in scope than the previous agreements between Prof. Mayr and BN. In particular, the 2004 agreement concerned Prof. Mayr's consultancy regarding myxoma virus, camelpox and other additional pox viruses whereas the previous agreements concerned only smallpox. D.I. 113, Ex. 46.

Regarding paragraph nos. 29-33, which relate to the U.S. Government MVA RFPs, BN notes the following:

BN met with U.S. Government officials prior to September 11th to explain their MVA technology and how their stand-alone vaccine could be used to safely vaccinate the entire U.S. population, including immunocompromised individuals. These meetings were instrumental in the U.S. Government's decision to stop purchasing ACAM1000 and ACAM2000 based on outdated Dryvax® technology and to invest in a new, safer MVA vaccine. Ex. V, Chaplin direct testimony, Q/A 25-30 at 18:18-26:11.

At the time RFP-1 was released, MVA-BN was already in clinical trials. Acambis, on the other hand, had not yet developed an MVA-based smallpox vaccine. [redacted]

Acambis went shopping for MVA, however, once it became clear that the U.S. Government intended to replace the traditional Dryvax vaccine with MVA. Acambis then entered into a Secrecy Agreement with BN on February 26, 2002 and met with BN on June 12, 2002 to discuss BN's MVA technology and to negotiate a potential license. Acambis had no MVA program prior to its meeting with BN. Ex. O, ITC Hearing Transcript, May 11, 2006, at 888:23-890:2. Personnel from Acambis and Bavarian Nordic met at Acambis' offices in Cambridge Massachusetts on June 12, 2002. Bavarian Nordic presented a slideshow presentation to Acambis. D.I. 116 at Ex. A, JSUF at ¶ 76. [redacted]

[redacted] The Acambis meeting included a detailed discussion of MVA-BN, Bavarian Nordic's animal testing models and replication data and information that would be needed to get a MVA program off the ground.

Although Acambis was recently notified by NIH that it is ineligible for a contract award under RFP-3, Acambis may still protest NIH's decision. Furthermore, in an ITC filing dated December 22, 2006, Acambis stated that [redacted] Ex. P, Acambis' Response to Commission at 33-34.

Acambis asserts that the MVA 572 used in its product, MVA3000, is "merely the starting point and must go through considerable processing and is combined with a proprietary recipe of other additives and diluents." D.I. 112, ¶ 34. This is incorrect.

The manufacturing process Acambis describes is irrelevant to the issue of conversion. The converted material is the MVA 572 or its progeny. The MVA 572 and its progeny was the necessary starting material for the final product MVA3000. That is, the converted material is the necessary starting material for producing millions of doses of the vaccine. In other words, but for the converted material the MVA3000 could not have been manufactured. The MVA virus is the drug substance and the active ingredient of the MVA3000 product. [redacted]

III. ARGUMENT

A. Statement of the Law

1. Summary Judgment Standard

Summary judgment is only appropriate when there are no genuine issues of material fact, which could preclude judgment for the moving party. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F. 2d. 1107, 1117 (Fed. Cir. 1985). The moving party bears the burden of establishing the absence of all genuine issues of material fact. *SRI Int'l*, 775 F.2d at 1116. A genuine issue of fact precluding summary judgment exists if sufficient evidence is presented such that a reasonable fact finder could decide the question in favor of the nonmoving party. *Anderson*, 477 U.S. at 248. When making a determination whether summary judgment is appropriate, the court must view all evidence and draw all reasonable inferences in a light most favorable to the nonmoving party. *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1320 (Fed. Cir. 2002). Moreover, caution should be exercised in deciding a motion for summary judgment, because such a motion is granted denies the nonmoving party its "day" in court. *SRI Int'l*, 775 F. 2d at 1116.

B. Conversion.

Acambis makes two main arguments that it should be entitled to summary judgment on BN's conversion claim. Neither of these are availing. First, Acambis attempts to shoehorn this case into nothing more than the conversion of an intangible "right to commercialize" MVA material to attempt to fit the circumstances of the *Miles* case, discussed below. *See Miles Inc. v. Scripps Clinic & Research Found.*, 810 F. Supp. 1091 (S.D. Ca. 1993). However, in *Miles*, the plaintiff specifically stipulated that the case would be decided by treating the property right at issue as conversion of the intangible "right to commercialize." *Miles*, 810 F. Supp. at 1093, n3. Plaintiff agreed "that the conversion claim is not as to the cell line itself," which was the underlying property. *Id.* at 1094. Here, Bavarian Nordic makes no such stipulation and has asserted conversion of its (or its predecessor Prof. Mayr's) physical, tangible, MVA material,

which Acambis was not authorized to receive from Dr. Moss, who received the material for research purposes only, and of which Acambis made unauthorized use. The MVA material itself, and its unique physical qualities, are both tangible and at issue. Thus, Acambis' arguments in sections I.B - I.D of its Opening Brief (D.I. 112) at pages 20 -27 fail, because Bavarian Nordic asserts conversion of tangible property rights through unauthorized transfer from Moss to Acambis and unauthorized use of that underlying MVA material in which Bavarian Nordic retains ownership.

Second, Acambis argues in section I.E. of its Opening Brief at pages 27 -30 that in any event, Bavarian Nordic should not prevail under a conversion theory because it has not been denied possession of the MVA material and has not been denied its own commercial use of the MVA material. This argument regarding BN's continued "control" over other MVA material similarly draws an improper and irrelevant analogy from the law of "intangible" property and mischaracterizes BN's interest in the tangible property at issue here and its use. (D.I. 112 at 27-30.)

These arguments are addressed in the sections below, which establish that BN's conversion claim is governed by well-settled law regarding a party's unauthorized use of another's property. BN also addressed its conversion claim in detail in its own separate summary judgment motion on the issue of conversion.

1. Acambis' Unauthorized Possession and Use of Bavarian Nordic's Property Is An Actionable Conversion of Tangible, Not Intangible, Property.

Acambis relies for its argument that BN does not have an actionable conversion claim almost exclusively on a California case, *Miles Inc. v. Scripps Clinic & Research Found.*, 810 F. Supp. 1091 (S.D. Ca. 1993). (D.I. 112 at 23-25.) *Miles*, however, was decided under circumstances that render it inapplicable to the present case. In *Miles*, the plaintiff explicitly stipulated that its conversion claim only involved a "right to commercialize" the physical property at issue (a cell line) and had no independent interest in that physical property. *Miles*,

810 F. Supp. at 1093 n.3. Indeed, the case had been remanded to the *Miles* court by the Ninth Circuit with specific instructions to consider implications of the intangible "right to commercialize" under California law, and the availability of the remedy of conversion to such an intangible right. *Id.* at 1094.

By contrast, BN has made no such stipulation that only a "right to commercialize" is at issue and has never limited its claim to such a right. To the contrary, BN is suing to recover the *physical virus material* in Acambis' possession and to recover damages for Acambis' unauthorized use of such material. Although *Miles* bears a superficial similarity to this case because both cases involve biological material, *Miles* concerns a different legal claim from the one at issue in this case which concerns tangible and not intangible property rights.

Attempting to shoehorn this case into the circumstances of *Miles*, Acambis argues in section I.B of its brief that BN is merely attempting to vindicate an intangible "right to commercialize" MVA. (D.I. 112 at 20-27.) Acambis' assertions are without foundation and thoroughly contradicted. Throughout this litigation, BN has consistently asserted its full ownership of MVA 572 and has directed its claim specifically at the tangible property—MVA virus material that Acambis was not authorized to receive and of which Acambis made unauthorized use. BN's description of the count in its First Amended Complaint nowhere limits the claim to the "right to commercialize"; rather, it states that "Bavarian Nordic has a valid, property interest in MVA 572 and its progeny *based on its ownership and exclusive license* from Professor Mayr with respect to MVA strains." (First Am. Compl. at ¶ 47 (D.I. 85); emphasis added.)

The only reference in the First Amended Complaint to a "right to commercialize" MVA 572 is explicitly within the context of Mayr and BN's full ownership of MVA 572 and its progeny. To this end, paragraph 48 of the First Amended Complaint states that "Prior to Bavarian Nordic's acquisition of *ownership of and commercial rights* in MVA strains from Professor Mayr, *ownership and the right to commercialize these strains* belonged exclusively to

Professor Mayr." (*Id.* at ¶ 48; emphasis added.) Acambis would simply ignore the "ownership" language of the count and prefer to address only the "right to commercialize" language, but that does not change the nature of the actual claim brought against Acambis.

Indeed, Acambis is well aware that BN's conversion count vindicates its full ownership of the strain because Acambis posed three interrogatories to BN concerning this very issue. In response to all three interrogatories, BN replied that its conversion claim was based on its full ownership of MVA 572, rather than any mere "right to commercialize" the strain. *See* Ex. R (Interrogatory Responses 1-3). Thus, in response to Interrogatory No. 1, in which Acambis inquired about the scope of BN's proprietary interest in MVA 572 and its progeny, BN replied (in relevant part):

> Bavarian Nordic has received *any and all rights* to the Modified Vaccinia Ankara ("MVA") vaccine stock and MVA viral stock developed by and/or in the possession of Prof. Mayr, including *without limitation* property rights, intellectual property rights, and damage and royalty claims for uses of said MVA and know how pertaining thereto, comprising claims for compensation against third parties accruing pre and post transfer of said rights to Bavarian Nordic.

Id. (emphasis added). BN included identical language in its response to Interrogatory 2, which inquired about the scope of "exclusive rights" that BN holds in MVA 572. *Id.* Acambis' Interrogatory No. 3 to BN was a contention interrogatory, directly inquiring about the basis of BN's conversion claim. While BN's response is too lengthy to quote in its entirety here, neither the phrase nor the concept of a "right to commercialize" appears in the response. *Id.* Rather, BN responds that its conversion claim arises from Acambis exceeding the "limited scope of [its] right to use MVA 572." Thus, both the First Amended Complaint and BN's interrogatory responses demonstrate that its asserted ownership of MVA 572 and its progeny is not limited to any mere "right to commercialize" the strain.

Indeed, it is unclear where Acambis finds the basis for this argument. Acambis cites to (without quoting) paragraph 51 of the First Amended Complaint as support for its "right to

commercialize" argument (*see* D.I. 112 at 22), yet that paragraph asserts precisely the opposite of Acambis' argument. The paragraph, in its entirety, reads as follows:

> Bavarian Nordic, the owner of exclusive rights in MVA 572, is entitled to the return of MVA 572 and/or its progeny based on its ownership through assignment of MVA strains, including MVA 572 and its progeny, and exclusive license from Professor Mayr to commercialize all such MVA strains.

(First Am. Compl. (D.I. 85) at ¶ 51.) Not only does BN explicitly base its right to relief in its "ownership" of MVA 572 and its progeny, but BN makes clear that it is suing Acambis in order to *physically repossess* the virus. Indeed, BN reiterates its demand for physical possession of the strain in its Prayer for Relief, in which BN demands "A return of all MVA virus and its progeny in the possession of Acambis and/or its suppliers to Bavarian Nordic." (*Id.*)

Acambis' attempts to mischaracterize Bavarian's claims for conversion of tangible continue. Acambis cites (without quotation) to paragraph 9 of Dr. Drillien's expert report to further its argument that only an intangible "right to commercialize" is involved in this case. (D.I. 112 at 22.) But, the only sentence remotely relevant to any "right to commercialize" is Dr. Drillien's statement that "I am prepared to testify on the conversion of the MVA 572 strain by Acambis for Acambis' commercial use." (D.I. 116 at Ex. I, Drillien Rep., at ¶ 9.) This sentence states that Acambis in fact made commercial use of BN's property, but in no way denotes or implies that BN's interest is limited to any "right to commercialize."

Finally, Acambis attempts to justify its argument by taking a phrase out of context from the report of BN's damages expert. (D.I. 112 at 22.) While the phrase admittedly references a "right to commercialize," the use of this isolated phrase occurs strictly within the context of evaluating the *damages* which BN has suffered, which obviously relate to the commercial value of the strain—much as the damages suffered by a plaintiff whose diamond ring were converted would also be related to the commercial value of the ring.

There is one thing that perhaps both parties can agree on, and that is that few if any cases implicate facts similar to those in this case: conversion claims typically involve inanimate objects,

not living organisms. The "living" aspect of the property in this case is highly relevant to BN's damages assessment, however, because once the vial of MVA 572 is converted, the viral products in the vial can replicate and produce millions of doses of valuable smallpox vaccine. Thus, while damages in this case are indeed computed based on Acambis' commercialization of the converted property, the conversion itself relates to the receipt by Dr. Moss of tangible MVA virus MVA 572, from Anton Mayr, and Acambis' receipt and unauthorized use of the progeny of that virus. To conclude based on BN's damages valuation that only a "right to commercialize" is at issue is not justified.

It is clear that MVA 572 is tangible property. Acambis has MVA 572 material in its freezers that it is not authorized to have or use, and which Bavarian Nordic is suing to repossess. Moreover, Acambis has made unauthorized use of additional MVA material that it sold to the U.S. Government, which is the subject of Bavarian Nordic's damages claim.

For the foregoing reasons, Bavarian Nordic's pleadings in this case clearly establish that it asserts conversion of tangible property, not intangible property. Thus, this case is quite different from the *Miles* case, which is premised in a stipulation that the converted property right is the intangible right to commercialize. *See Miles*, 810 F. Supp. at 1093, 1094.

In section I.C. of its brief, Acambis argues that the *Miles* case prevents a plaintiff from recovering under a conversion theory where the intangible right to commercialize is the sole property right asserted. However, as discussed above, BN bases its conversion claim on a conversion of tangible property, and therefore Acambis' argument is unavailing.

Even if *Miles* were relevant to BN's conversion claim, however, Acambis repeatedly misconstrues the *Miles* court's reasoning. For example, Acambis cobbles together phrases from *Miles* to suggest that an action does not lie in conversion where rights could be vindicated under patent or contract law (D.I. 112 at 24.) But in fact, the *Miles* court specifically declares that "This decision *does not* rest on the fact that other remedies exist for a party in Plaintiff's position." *Id.* at 1096 n.6 (emphasis added). Similarly, Acambis combines sentences from two

different paragraphs—without so noting—in order to imply that because "parties developing the cell lines are sophisticated researchers capable of protecting themselves legally," their disputes should be lie in contract or patent. (D.I. 112 at 24 (quoting *Miles*, 810 F. Supp. at 1097).) In its original context, however, the *Miles* court used the above-quoted phrase to explain why a finding of conversion was unlikely to have a drastically chilling effect on medical research, as a prior court had predicted. *Id.* Thus, the *Miles* case is both irrelevant to the current case and, in any event, misapplied by Acambis.

In section I.D., Acambis builds on its specious argument that Bavarian Nordic asserts conversion only of an intangible property right. In particular, it argues that Bavarian Nordic cannot recover under a conversion theory because the asserted intangible right is not merged into a document, like a stock certificate. *See, e.g.*, D.I. 112 at 21 and 26-27. At this point, Acambis' argument reveals the extent to which it is strained. The property here has nothing to do with negotiable instruments like stock certificates, or the merger of intangible rights into such documents. Rather, the property here comprises Bavarian Nordic's MVA virus because of the desirable physical properties of that virus. In short, Acambis' argument regarding the "right to commercialize" is directed at a straw man.

Bavarian Nordic's claim is predicated on its full ownership of tangible property— MVA 572 and its progeny—and the misuse and unauthorized possession of that virus. As discussed in detail in Bavarian Nordic's opening brief, the most applicable line of cases is that concerning a bailee's unauthorized use of another's physical property. The *Miles* court did not and could not address these cases because the issue in *Miles* was framed in terms of intangible property.

2. Acambis' Unauthorized Possession and Use of MVA 572 and Its Progeny Deprives Bavarian Nordic of Control Over Its Property.

Acambis' second major argument, raised in section 1.E. of its brief, is that it did not convert BN's property because BN retains additional vials of MVA 572 besides the ones currently in Acambis' possession. (D.I. 112 at 27-30.) As such, Acambis asserts, it has not

deprived BN of the use of all MVA 572 in the world or of commercial uses, but only the particular vials of the virus in Acambis' freezers. (*Id.*) Yet Acambis' argument receives no support from the cases it cites. Nor does the argument comport with common sense. This is the same as saying that if I have three SAAB cars and lend one of them to a friend for personal use, who sells or profitably leases it, then I cannot recover for conversion because I have two more SAAB card at home.

In every case cited by Acambis where the court declined to find conversion, the property concerned was an intangible right—e.g., information, or an idea. *See Orteck Int'l, Inc. v. Transpacific Tire & Wheel, Inc.*, 2006 U.S. Dist. LEXIS 67702, *76 (D. Md. 2006) (allegedly converted property is a customer list); *Duty Free Americas, Inc. v. Legg Mason Wood Walker, Inc.*, No. 24-C-04-005696, 2005 WL 914395, at *2 (Md. Cir. Ct. Jan. 13, 2005) (allegedly converted property is a trade secret); *Home Paramount Pest Control Cos., Inc. v. FMC Corp. Prods. Group.*, 107 F. Supp. 2d 684, 693 (D. Md. 2000) (allegedly converted property is a customer list); *Fainsbert v. Cuthbert*, No. 06-2017, 2006 WL 2096057, at *5-6 (D.N.J. July 27, 2006) (allegedly converted property is secret financial information); *Furash & Co., Inc. v. McClave*, 130 F. Supp. 2d 48, 58 (D.D.C. 2001) (allegedly converted property is trade secrets); *Pearson v. Dodd*, 410 F.2d 701, 706 (D.C. Cir. 1969) (allegedly converted property is secret business information). In each of these cases, the court declined to find a conversion because the owner retained the benefit of the intangible ideas that actually comprised the property.

In this case, however, the property in question is *not* an intangible idea. It is a physical virus having desirable physical qualities. Acambis sold five hundred thousand vials of this virus to the U.S. Government, which currently sit in freezers where BN can exercise no control over them and Acambis retains MVA that it was not authorized to receive.

In the one case cited by Acambis where the property in question was in fact a physical commodity—rather than an intangible right—the court indeed held that the commodity was converted. *See Pagliai v. Del Re*, No. 99-CIV-9030 (DLC), 2001 WL 220013, at *5-6 (S.D.N.Y.

Mar. 7, 2001) (the property is a painting, and court holds that it was converted). Indeed, *Pagliai* is particularly relevant to the facts of the current case because the conversion in *Pagliai* occurred while the defendant had lawful possession the painting in a bailment context, but then sold the painting without authorization. *Id.*

Unlike the trade secrets, customer lists, and other business information at issue in the cases cited by Acambis, and as explained in Bavarian Nordic's opening brief in support of its motion for summary judgment on the issue of conversion (D.I. 115), MVA 572 is tangible property. Its value is not that it contains information, or communicates an interesting idea, but that it has physical properties allowing it, when injected physically into your body, to immunize you against smallpox. While BN may possesses other vials of this virus, BN has been deprived of the ability to assert ownership or control over the specific vials of MVA material in Acambis' possession, which Acambis acquired without authorization and used without authorization to compete for government contracts to supply MVA to the U.S. Government for millions of dollars. Under Acambis' all-or-nothing approach, one does not convert an owner's property unless one converts *all* of an owner's property. This is simply not the law.

As explained more extensively in BN's opening brief (D.I. 115), a party's unauthorized use of property entrusted to him for a particular purpose is a conversion: "when he departs from the object of the bailment, it amounts to a conversion of the property." *Hall v. Corcoran*, 107 Mass. 251, 255 (Mass. 1871); s*ee also Goell v. Smith*, 128 Mass. 238, 239-240 (Mass. 1880) ("where the violation of the terms of the agreement tends to show the assumption of dominion over, and ownership of, the chattel, it is evidence tending to show a conversion of it to his own use by the lessee or bailee.").[1] This is the case, regardless of the fact that the owner has parted

[1] Acambis asserts, and Bavarian Nordic does not dispute, that Massachusetts law applies to the conversion claim. (D.I. 112 18-20.)

with possession of the property during the term of the bailment and regardless of whether the owner retains other, similar property.

The Restatement (Second) of Torts also summarizes this principle: "One who is authorized to make a particular use of a chattel, and uses it in a manner exceeding the authorization, is subject to liability for conversion to another whose right to control the use of the chattel is thereby seriously violated." Restatement (Second) of Torts, § 228. And as *comment a* to the Restatement section elaborates, the principle applies not only to a bailee but also to "a servant, an independent contractor, a gratuitous user, or any other person permitted to use the chattel." *Id.* It applies not only when the restriction on use is explicit, but also when the restriction is implied. *See* Richard A. Epstein, *Torts* § 1.12.3 "Specialized Cases of Conversion" (Aspen 1999). Indeed, this rule of law was already "well-recognized" in 1916, where it was stated by a court in Delaware:

> it is a well-recognized rule of law, that if personal property is sold without the consent of the owner by one who has only a temporary right to its use by lending, or otherwise, *or a qualified possession of it for a specific purpose, as for personal use, the owner can follow and reclaim it in the hands of any person*, how-ever innocent.

McClemy v. Brown, 99 A. 48, 50 (Sup. Ct. Del. 1916) (emphasis added).

In this case, NIH was not authorized to provide Acambis with the MVA 572 progeny in its possession—that BN (and previously Anton Mayr) owned. Acambis nonetheless accepted the virus from the NIH and used it in an unauthorized manner to compete with BN and sell the material to the U.S. Government. As the "well-recognized" law of conversion states, that is a conversion. As such, the factual basis exists for a reasonable jury to conclude that Bavarian Nordic, and not Acambis, is entitled to summary judgment on the conversion claim.

C. Unfair Competition Under the Lanham Act and Delaware Law

Acambis attempts to avoid at least some of the unfair competition claims by arguing that the present case should be decided in the same manner as the *Dastar* and *Monsanto* cases. However, in order to do so, Acambis argues that the unauthorized use and replication of a viral

product is analogous to the unauthorized use and copying of a copyrighted television series. This is, to say the least, a stretch.

The *Dastar* and *Monsanto* opinions are simply not analogous when considering that nothing was "copied" in the present case. Viruses "replicate" and essentially make replicates of themselves. A "replicate" is not a copy, in the traditional sense of copyright law, because a copy means that you take identical content and reproduce it onto a different media, such as a different compact disk, digital video disk, etc. When dealing with live, biological materials, as in the present case, the replicates are new versions of the original virus. The replicates may or may not have the same properties, but often have the same genomic make up. Here, Acambis took the replicates, or progeny, of MVA 572 and, after screening for the properties described in BN's patents, used the progeny to make its commercial product. When marketing this commercial product as ACAM3000, Acambis "reverse passed off" what amounted to BN's product as their own. Thus, there is no copying of BN's converted vaccinia virus, MVA 572, but the harvesting of self-replicating progeny of BN's MVA 572 and offering for sale that progeny as an Acambis product when in fact it is a BN product.

Acambis has predicated its argument that Acambis has not committed any actionable violation under the Lanham Act or Delaware Law by: (i) mischaracterizing the facts pertaining to its sale of the MVA 572 virus as being limited to copying a component of the MVA virus, as opposed to its deliberate reproduction and the whole MVA virus and relabeling the whole MVA virus using its trade name "ACAM" to try to bring this case within the purview of the *Dastar* and *Monsanto* cases; (ii) ignoring explicit and false statements made by Acambis in its advertising and responses to RFP's, and instead treating them as "impliedly misleading;" and (iii) not addressing Acambis' pattern of misconduct. As established below, Acambis' motion thus attempts to shoe-horn an incorrect statement of facts into law that does not fit the facts of this case.

1. Bavarian Nordic Can Prove a False Representation of Origin

Acambis argues that Bavarian Nordic cannot prove that Acambis made a false designation of origin under the Lanham Act because "reverse passing off" only applies to misrepresentations concerning the final product. Acambis relies for its argument on *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003) and *Monsanto Co. v. Syngenta Seeds, Inc.*, No. 04-305, 2006 U.S. Dist. LEXIS 54515 (D. Del Aug. 4, 2006) (Robinson, C.J.), which relies on the holding in *Dastar* to reject a false designation of origin claim.

However, Acambis has offered no facts that support a *Monsanto* or *Dastar* outcome, and there are none. The *Dastar* and *Monsanto* cases stand for the proposition that the term "origin" in § 43(a) claims under the Lanham Act is broad enough to encompass reverse passing off claims, but cannot be extended to cover the failure to acknowledge a contribution, particularly of intellectually property, to a final product. The cases do not alter the basic jurisprudence that reselling another's product as one's own is reverse passing off.

In *Dastar*, the plaintiff took an uncopyrighted television series, modified them, and sold them under the title "World War II Campaigns in Europe." *Dastar*, 539 U.S. at 26-27. This Court characterized the differences between plaintiff's and defendant's video series in Dastar as:

> Dastar's Campaigns series is slightly more than half as long as the original Crusade television series. Dastar substituted a new opening sequence, credit page, and final closing for those of the Crusade television series; inserted new chapter-title sequences and narrated chapter introductions; moved the "recap" in the Crusade television series to the beginning and retitled it as a "preview"; and removed references to images of the book. Dastar created new packaging for its Campaigns series and . . . a new title.

Monsanto, 2006 U.S. Dist. LEXIS 54515 at *7 - 8. The Supreme Court in *Dastar* noted the basic difference between "communicative goods," such as videos and books, that are valued for the ideas that they contain, as opposed to goods that are valued for their "physical qualities." *Dastar*, 539 U.S. at 33. The Court then refused to require "attribution" for the creative work conveyed by the videos because this would "create a species of mutant copyright law." *Id.* at 34.

In *Monsanto*, Monsanto argued that Syngenta's crossing of Monsanto's inbred corn line containing a "trait," known as the GA21 trait, with another inbred corn line to create a hybrid seed without modifying the GA21 trait, is akin to simply repackaging Monsanto's product and thus reverse passing off. *Monsanto*, 2006 U.S. Dist. LEXIS 54515 at *9. The dispute in *Monsanto* boiled down to whether GA21 trait is the product, or whether the whole seed containing the GA21 trait is the product. *Id.* This Court decided that the seed was the product and "decline[d] to consider Syngenta's hybrid seed containing the GA21 trait to be "merely repackag[ing]" noting that "[w]hether the trait contained in the seed is the intellectual property of another, is a question for the intellectual property laws. *Id.* at *9-10.

The present case, by contrast, Acambis admits to "copying" the whole MVA 572 virus seed, rather than just part of it. *See* Acambis' Op. Brf., D.I. 112, *passim*. In other words, Acambis reproduced Prof. Mayr's and later Bavarian Nordic's MVA 572 virus seed because of its desirable physical qualities and repackaged and sold the progeny of the MVA 572 virus under the name "ACAM 3000." Unlike the *Dastar* case, the MVA viruses are not "communicative goods" and are valued for their physical characteristics, not the ideas they convey. Moreover, unlike *Dastar* where the defendant had made significant editorial changes to the television series, Acambis merely took self-replicating progeny of BN's MVA virus, without seeking to make any changes to the MVA virus, and passed it off as its own.

With respect to the *Monsanto* case, Acambis has not copied a trait into a seed, but instead has misappropriated the replicates of the MVA 572 virus. Acambis used the trademark "ACAM3000" to refer both to individual MVA viruses or "seeds" that it derived from MVA 572 and to the packaged form in which millions of the MVA viruses are packaged in each vial of ACAM3000.

Thus, Acambis' product is being passed off as essentially BN's product and Acambis' actions are merely a repackaging and relabeling of BN's MVA virus. Thus nothing in Acambis' submissions refute BN's claim of reverse passing off or misrepresentation of origin under the

Lanham Act. *See Dastar* at 28 (citing *Williams v. Curtiss-Wright Corp.*, 691 F.2d 168, 172 (3d Cir. 1982).

Consistent with a claim of reverse passing off, the evidence in this case shows that Acambis sold different viruses in the vaccinia virus family under the trade names "ACAM1000" and "ACAM2000." *See* Lee Tr., 934-935, attached as Exhibit O; CBER Comments Regarding the MVA IND at AC00092061, attached as Exhibit S. The "ACAM" identifies "Acambis" as the originator of the goods when they were not. *Id.* These viruses were a replicating form of vaccinia virus. In stark contrast, "ACAM3000" product is BN's (and previously Anton Mayr's) MVA, which is physically different from and has very different replication characteristics from the ACAM1000 and ACAM2000 products. With respect to usage of the trademark, Acambis used ACAM3000 to identify the MVA virus seed itself and to the packaged form of the MVA virus sold to the U.S. Government in vials containing millions of individual MVA viruses. An agency of the U.S. Government, the Food and Drug Administration, in fact found this labeling confusing given the differences between Anton Mayr's MVA, which Acambis called ACAM3000, and the ACAM1000 and ACAM2000 viruses, which are not considered MVA viruses. The FDA asked Acambis to change the name because of the inherent confusion. *See* Lee Tr., 934-935, attached as Exhibit O; *see* also CBER Comments Regarding the MVA IND at AC00092061, attached as Exhibit S.

For the foregoing reasons, the facts of this case do not support extending the *Dastar* and *Monsanto* rationale to cover Acambis' misconduct and a sufficient factual basis exists for a reasonable jury to find that Acambis misrepresented the origin of its ACAM3000 product.

2. Bavarian Nordic Can Prove False Advertising

Acambis' arguments that Bavarian Nordic cannot support a false advertising claim are found in two short paragraphs on pages 33 and 34 of its Opening Brief (D.I. 112). The argument boils down to Acambis' assertion that Bavarian Nordic's false advertising claim is not distinguishable from its false representation of origin claims, and therefore *Dastar* and *Monsanto*

prevent recovery. But, as discussed immediately above, *Dastar* and *Monsanto* are not applicable here because Acambis has merely repackaged and sold Bavarian Nordic's MVA virus seed. Similarly, Acambis' misrepresentations and false statements relate to the whole MVA virus—Bavarian Nordic's (and previously Anton Mayr's virus)—which Acambis calls ACAM 3000 in both its packaged and unpackaged form.

In this regard, and as identified in Bavarian Nordic's interrogatory responses (*see* Exhibit T), *inter alia*:

(i) Acambis falsely stated to the U.S. Government in Acambis' January 14, 2003 that switching to the Moss-provided strain [redacted] *See* D.I. 116 at Ex. BB (AC0012113). But, Acambis conducted an in-depth review of the MVA-TBC strain and was well aware of the potential "cloud" on its ability to commercialize MVA. (*See e.g.*, D.I. 116 at Ex. BB (AC0012119; AC0012113; AC0012414; AC0011704); Ex.U, McAvoy Dep. at 119:3-120:22.) Indeed, the January 12, 2003 Business Officer's Report by Nicholas Higgins notes that negotiations with Therion stalled because Therion did not have good title to commercialize MVA. (D.I. 116 at Ex. CC, AC0217051.) Moreover, in a December 24, 2002 email, Thomas Monath notes that [redacted] (D.I. 116 at Ex. DD, AC0336880; *see also* AC0336980) And the false statement was made just several days after Stephen Atkinson's clear statement of the risks to Acambis of using the MVA-TBC strain:

[redacted]

(D.I. 116 at Ex. DD, AC0336881.) Indeed, Atkinson concluded that Acambis would need [redacted]

[redacted] (*Id.*; *see also* D.I. 116 at Ex. EE, TBC00880.)

(ii) Acambis falsely stated to the NIH on February 4, 2004, in its "Plan to License and Patent New MVA Vaccine" section of its response to the second RFP, that [redacted] (Ex. W at AC0012089.)

Acambis does not address the falsity of any of Acambis' statements identified by Bavarian Nordic in its interrogatory responses, including those above, because those statements are false and likely to cause confusion and, sadly, in the context of the U.S. Government's "Bioshield" program, could potentially cause catastrophic consequences to the U.S. Government and people by putting the government in a position of choosing a supplier that may not have the freedom to supply the product when needed. In addition, this put Bavarian Nordic at a competitive disadvantage and caused it to be denied compensation for the use of its property.

These false statements are related to the nature, characteristics and qualities of the Acambis product as well as the approval or authorization necessary to use the product. Therefore, contrary to Acambis assertions, and as demonstrated above, the factual basis is here for a reasonable jury to find that Acambis did engage in false advertising.

3. Bavarian Nordic Can Prove Consumer Confusion

Acambis argues that Bavarian Nordic has not identified any evidence of confusion by the U.S. Government with respect to the false advertising and misrepresentation of origin claims. However, Acambis is incorrect.

First, as Bavarian Nordic identified in its interrogatory responses, the U.S. Government—the FDA—found Acambis' labeling of its MVA virus product ACAM3000 "confusing" because it associates Anton Mayr's MVA (later Bavarian Nordic's MVA) with Acambis' product line, which is very different. *See* Second Supplemental Response to Interrogatory No. 8 at page 3;

FDA document (Ex. S at AC00092061). The ACAM3000 name also misleadingly implies that the vaccine is derived from ACAM2000, much as ACAM2000 is in fact derived from ACAM1000. *See* Second Supplemental Response to Interrogatory No. 8 at page 10 (Ex. T); Lee Tr. at 888-89 (Ex. O). This evidence reflects confusion as to the source of the virus.

Second, for Bavarian Nordic's false advertising claims, Bavarian Nordic has demonstrated several instances in which Acambis made literally false representations to the U.S. Government regarding Acambis' freedom to operate with MVA. In cases of literal falsity, confusion is presumed. *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939 (D.N.J. 1993) ("because the district court properly found that claims in this case were literally false, it did not err in ignoring Penzoil's superfluous evidence relating to the absence of consumer confusion.").

Third, Acambis' argument may be considered in the context of the following analogy to the facts of this case: The U.S. Government provides Pepsi Cola to the Coca-Cola Company, and the Coca-Cola Company repackages the Pepsi Cola and sells it back to the U.S. Government, relabeled with the "Coca-Cola" name and various falsities and misrepresentations about the product itself and Coca-Cola's ability to perform under the contract without interference from third parties. Under these circumstances, confusion regarding the products is inevitable and it would not be surprising for another agency to flag the labeling as problematic and confusing as the FDA did with Acambis' products.

For the foregoing reasons, an adequate factual basis exists for a reasonable jury to find confusion as to instances of misrepresentation of origin and false advertising.

4. Bavarian Nordic Is Entitled to Recover Under the Delaware Law of Unfair Competition and Deceptive Trade Practices

Acambis argues that Bavarian Nordic's claims under the Delaware Deceptive Trade Practices Act ("DDTPA") and Delaware common law are governed by the same facts and legal standards as the Lanham Act and therefore that they should be dismissed. However, as discussed

above, Bavarian Nordic has viable claims for Acambis' violation of § 43(a) of the Lanham Act. Therefore, Acambis' argument fails.

Acambis argues that Bavarian Nordic cannot prove a violation of subsections (1) or (2) of the DDTPA which relate to false designation of origin under the Lanham Act because of the *Dastar* and *Monsanto* cases discussed and distinguished above. Acambis' argument fails for the same reasons discussed above—Acambis has essentially "repackaged" progeny of BN's MVA 572 and labeled it as if it were an Acambis product "ACAM3000," both with respect to the individual MVA viruses themselves and those viruses packaged in a vial and sold. This is the traditional reverse passing off scenario acknowledged in *Dastar* as actionable under § 43(a). Thus the legal and factual basis exists for a reasonable jury to conclude that Acambis' conduct is actionable under subsections (1) and (2) of the DDTPA.

Acambis argues that BN cannot prove a violation of subsections (5) and (7) of the DDTPA because BN has not identified any false representations, but only "implied misrepresentations." Here Acambis is incorrect about the facts and therefore cites inapplicable law. As discussed above with reference to the Lanham Act, Bavarian Nordic has identified several statements in Acambis' advertising and RFP responses that are explicitly false, and not merely "implied misrepresentations." Therefore, the legal and factual basis exists for a reasonable jury to find that Acambis did falsely advertise under subsections (5) and (7) of the DDTPA.

Acambis argues that BN cannot prove a violation of subsections (2), (3) and (12) of the DDTPA because BN has not alleged that Acambis improperly used any trademark, service mark, certification mark or collective mark in its RFP responses, citing the *Delaware Solid Waste Authority* case. This is incorrect for two reasons.

First, the *Delaware Solid Waste Authority* is an unpublished opinion and on its face only applies the standard that Acambis attributes to the case in analyzing subsections 2 and 3 of the DDTPA. Subsection 12 is, which is a "catch-all" section discussed below, uses different

language than subsections 2 and 3 and was analyzed differently, and without reference to "trademarks" or "tradenames."

Second, subsections 2 and 3 of the DDTPA on their face are applicable to reverse passing off, contemplating conduct that "causes likelihood of confusion or of misunderstanding as to the source …", in the case of subsection 2, and "causes likelihood of confusion or of misunderstanding as to affiliation, connection …," in the case of subsection 3. There is no mention in these subsections of the use of marks, such as "trademarks, service marks, certification marks, or collective marks" that Acambis and the *Delaware Solid Waste Authority* case attribute to them. As Bavarian Nordic has demonstrated with respect to its Lanham Act claims, Acambis' product has created confusion as the source of its goods and its affiliation and connection with Bavarian Nordic's and previously Mayr's MVA by, *inter alia*, its reverse passing off an false statements regarding its freedom to operate discussed above.

Third, with respect to subsection 12 of the DDTPA, the catchall section, and generally with respect to Acambis' unfair competition claim, Acambis has ignored the facts that Bavarian Nordic has identified in its interrogatories as Acambis' unfair competition, defective trade practices and pretended that it has discussed the full extent of the law of unfair competition, which it defines narrowly and as co-extensive with the Lanham Act. However, it is clear that the law of unfair competition in Delaware is not so constrained and that there are many facts that Bavarian Nordic has identified, going beyond those identified here as reverse passing off and false advertising to rebut Acambis' summary judgment motion, upon which a reasonable juror could find unfair competition or a violation of subsection 12 of the DDTPA, or other subsections for that matter.

Delaware's common law of unfair competition was codified by the Uniform Deceptive Trade Practices Act, which was, in turn, codified as Delaware's Deceptive Trade Practices Act ("DTPA"). *See* 6 Del. C. § 2532; *State ex rel. Brady v. Wellington Homes, Inc.*, 2003 WL 22048231 *1 (Del. Super., Aug. 20, 2003). Generally, unfair competition is "conduct of business

[that] is part of a heterogeneous collection of legal wrongs known as 'unfair trade practices.'" *State ex rel. Brady v. Wellington Homes, Inc.*, 2003 WL 22048231 at *1.

Contrary to Acambis' contentions, a claim of unfair competition is not neatly compartmentalized. Rather, unfair competition is a "flexible and elastic concept" where the "metes and bounds [of unfair competition law] have not been charted." *State ex rel. Brady v. Wellington Homes, Inc.*, 2003 WL 22048231 at *1; *Ryan v. Carmona Bolen Home for Funerals*, 775 A.2d 87 (N.J. Super. 2001).

> [T]he essence of unfair competition is fair play. Thus, the purpose of the law regarding unfair competition is to promote higher ethical standards in the business world. Accordingly, the concept is deemed as flexible and elastic as the evolving standards of commercial morality demand. The judicial goal should be to discourage, or prohibit the use of misleading or deceptive practices which renders competition unfair. The law must be sufficiently flexible to accommodate those goals (internal citations omitted).

Ryan, 775 A.2d at 92. Similarly, in *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 531 (1935), the United States Supreme Court stated:

> [The] scope [of unfair competition] has been extended. It has been held to apply to misappropriation as well as misrepresentation, to the selling of another's goods as one's own--to misappropriation of what equitably belongs to a competitor. Unfairness in competition has been predicated of acts which lie outside the ordinary course of business and are tainted by fraud or coercion or conduct otherwise prohibited by law (internal citations omitted).

Id. at 531.

"Unfair Competition" at common law, generally speaking, has referred to unfair competition between businesses or trades. *See State ex rel. Brady,* 2005 WL 22048231, at *1. Delaware courts have turned to the Restatement (Third) of Unfair Competition for aspects of unfair competition law. *See Delaware Exp. Shuttle, Inc. v. Older,* 2002 WL 31458243, at *18 (Del. Ch. Oct. 23, 2002). The Restatement (Third) of Unfair Competition includes a broader range of unfair competition claims, including certain patterns of objectionable practices.

See Restatement (Third) of Unfair Competition §1 (1995); *see also Synthes (U.S.A.) v. Globus Medical, Inc.*, 2005 WL 2233441, *9 (E.D. Pa. Sept. 14, 2005) (stating that the Restatement includes a residual category encompassing other business practices determined to be unfair, known as a "catch-all" category); *Warner Lambert Co. v. Purepac Pharm Co.*, 2000 WL 34213890, *10 (D.N.J. Dec. 22, 2000) ("Courts continue to evaluate competitive practices against generalized standards of fairness and social utility."). In fact, a primary purpose of unfair competition laws is to redress objectionable patterns of business practices. *See Synthes (U.S.A.)*, 2005 WL 2233441 at *9 ("A primary purpose of the law of unfair competition is the identification and redress of business practices that hinder rather than promote the efficient operation of the market.").

Acambis' pattern of misconduct includes, established in Bavarian Nordic's Second Supplemental Response to Interrogatory No. 8 (attached hereto as Exhibit T):

(i) Acambis knew but did not disclose to the U.S. Government the risk that Anton Mayr and/or Bavarian Nordic could sue Acambis' manufacturing partner Baxter in Austria to enjoin Baxter from using the MVA 572 property to manufacture protective vaccine to safeguard the U.S. population in the event of an outbreak;

(ii) Acambis ended negotiations with Bavarian Nordic to pay millions of dollars for MVA material from Bavarian Nordic or Therion to instead get it for free and use it from a known, unauthorized source. At least as early as September 19, 2002, however, Acambis realized that the government would not reimburse Acambis for the costs of licensing MVA from Therion, and that Acambis and Baxter would thus have to absorb the entire cost of the Therion license themselves. *See* Ex. W at AC0336538. [redacted] *See* Ex. W at AC0336945.

(iii) Acambis exerted improper influence on the decision making process to assure a grant under the RFP process and an improper influence on Dr. Moss to encourage key employees

at NIH to advance the MVA strain to Acambis and Baxter without authorization from Mayr or Bavarian Nordic. In this regard, Moss, Acambis' consultant, gave Acambis special treatment, giving Acambis the MVA virus, but denied it to Therion. *See* D.I. 116 at Ex. X, 2/26/2002 Gritz letter to Mayr ("Moss is willing to send us the virus but would like written permission from you before he sends us the virus.") Indeed, Mayr had specifically reiterated to Moss that the strain was for academic research. (*See* D.I. 116 at Ex. Y, 11/6/2002 letter from Mayr to Moss.) And agents of Acambis were also on notice in 2002 that "the MVA strain which Dr. Moss had received from Anton Mayr was proprietary to Bavarian Nordic and could not be distributed to others" by virtue of their failed negotiations with Therion. *See* D.I. 116 at Ex. EE, TBC00580. And, Acambis was willing to give Moss a cut of the windfall as well, as demonstrated in a June 21, 2003 email from Tom Monath: [redacted] (Ex. W at AC0450441) (emphasis added);

(iv) Moss had been a consultant for Acambis' predecessor company, OraVax, and had received at least [redacted] from Acambis/OraVax between the years of 1998 and 2002. (Ex. B at DBM 005; DMB 021; DMB 088.) Upon Acambis' receiving a contract to provide a Dryvax-based smallpox vaccine to the U.S. government, however, HHS ethics requirements forced to Moss to sever his consultancy agreement, but he advised Acambis that he would continue to consult for them "informally." (Ex. B at DMB 081.) And indeed, in addition to supplying Acambis with the strain he derived from Mayr's MVA 572 strain, Moss worked closely with Thomas Monath to evaluate and disparage Bavarian Nordic's intellectual property rights in MVA. (Ex. W at AC0410318; AC0409328; AC0409496; B003941)(D.I. 116 at Ex. Z, TBC 00580). And even prior to the issuance of the first RFP, Monath used his connections with Moss to obtain inside information about Acambis' competitive prospects vis-à-vis Bavarian Nordic, asking Moss to [redacted]

[redacted] (Ex. W at AC0349038.) On at least one occasion Dr. Moss provided Bavarian Nordic confidential business information to Acambis, including the status of Bavarian Nordic's clinical trials and developments related to Bavarian Nordic's MVA program. (Ex. W at AC0011265-11269.)

(v) Acambis conducted an in-depth review of the MVA-TBC strain and was well aware of the potential "cloud" on its ability to commercialize MVA. (*See e.g.*, Ex. W at AC0012119; AC0012113; AC0012414; AC0011704; *and* D.I. 116 at Ex.BB, McAvoy Dep. at 119:3-120:22). Indeed, the January 12, 2003 Business Officer's Report by Nicholas Higgins notes that negotiations with Therion stalled because Therion did not have good title to commercialize MVA. (D.I. 116 at Ex. CC, AC0217051) Moreover, in a December 24, 2002 email, Thomas Monath notes that [redacted] (D.I. 116 at Ex. DD, AC0336880; *see also* AC0336980) And this statement was made just several days after Stephen Atkinson's clear statement of the risks to Acambis of using the MVA-TBC strain:

[redacted]

(D.I. 116 at Ex. DD, AC0336881) Indeed, Atkinson concluded that Acambis would need [redacted] (*Id.*; *see also* D.I. 116 at Ex. EE, TBC00880) Yet Acambis never informed the NIH that the risks associated with the Therion strain also pertained to the strain received from Moss. To the contrary, Acambis' January 14, 2003 letter to NIH falsely states that switching to the Moss-provided strain [redacted] *See* D.I. 116 at Ex. BB, AC0012113.

(vi) Acambis falsely stated to the NIH that the NIH itself had made the requisite determinations of freedom to operate: [redacted] (Ex. W at AC0012101; *see also* AC0012086.) Moreover, Acambis falsely stated to the government on February 4, 2004, in its "Plan to License and Patent New MVA Vaccine" section of its response to the second RFP, that [redacted] (Ex. W at AC0012089.)

(vii) Acambis deliberately engaged in this pattern of conduct to make NIH believe that there were no questions concerning Acambis' freedom to operate and no risks concerning its supply of MVA to the U.S. Government so that it could win lucrative contracts, which it in fact won, and so that it could do so without compensating its competitor Bavarian Nordic for the use of its property.

(viii) Acambis made unauthorized use of Bavarian Nordic's, and previously Anton Mayr's MVA, and resold that MVA under Acambis' trade name ACAM3000, which refers both to the MVA virus and to millions of the MVA viruses packaged in vials, thus amounting to reverse passing off.

Granting summary judgment to Acambis on these facts would undermine the purpose of unfair competition laws and would allow Acambis to profit from its multiple acts of wrongdoing and pattern of misconduct, which a reasonable jury could find sufficient to establish unfair competition or a deceptive trade practice under Delaware law, including one of the "catch all" sections.

VI. CONCLUSION

For all of the reasons set forth above, Acambis' motion to dismiss, or in the alternative for summary judgment, on all claims (D.I. 111), should be denied in its entirety.

January 3, 2007

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on January 10, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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